Report of JONATHAN BORAK, MD, DABT

I am an Associate Clinical Professor of Epidemiology & Public Health and Medicine at Yale University, Director of the Yale University Interdisciplinary Risk Assessment Forum and a faculty member of the Yale Occupational and Environmental Medicine Program. Among my Yale activities, I direct and teach required graduate-level courses in Toxicology and in Risk Assessment.

I am also President of Jonathan Borak & Company, a consulting firm in New Haven, Connecticut, and Adjunct Associate Professor of Medicine at The Johns Hopkins University. From 1979 to 1988, I was the Director of Emergency Services at Hospital of St. Raphael in New Haven, Connecticut, where I was responsible for the clinical, administrative and EMS operations of an emergency department and trauma facility.

I received my B.A. with honors from Amherst College in 1968 and my M.D. from New York University in 1972. I am Board Certified in Internal Medicine, Preventive Medicine (Occupational Medicine) and Toxicology (American Board of Toxicology). I am a Fellow of the American College of Physicians, a Fellow of the American College of Occupational and Environmental Medicine and a Fellow of the Royal College of Physicians of Canada.

I served as an elected Director of the American College of Occupational and Environmental Medicine (ACOEM) from 1999-2002 and currently serve as Chair of the ACOEM Council on Scientific Affairs. I was Editor and Course Director of the ACOEM *Core Curriculum in Environmental Medicine*, Sessions Chair of the 1998 American Occupational Health Conference and Scientific Chair of the 1993 ACOEM State-of-the - Art Conference. I have received numerous awards from ACOEM including: the President's Award in 1994 and 2000; the Adolph G. Kammer Merit in Authorship Award in 2003; the Robert A. Kehoe Award of Merit in 2004; and the George H. Gerchman Memorial Prize in 2005.

I have written numerous books, monographs, book chapters, peer-reviewed articles and other publications on a range of topics in occupational medicine, toxicology, epidemiology and industrial hygiene. Included among those are two critical reviews on issues involving occupational beryllium exposure and chronic beryllium disease (1,2) that were published during the past year.

I am also a member of the Editorial Boards of *Journal of Occupational and Environmental Hygiene* and *Journal of Occupational and Environmental Medicine*. I served as Associate Editor of *OEM Report*, as a member of the Editorial Board of the *American Industrial Hygiene Association Journal*, and continue to serve as a peer reviewer for numerous medical and scientific publications. I have served as a member of National Advisory Committees of the US EPA and the National Research Council, and on National committees of the American Industrial Hygiene Association, American College of Emergency

Physicians, ACOEM, and the National Faculty of the American Heart Association. My current Curriculum Vita is attached to this Report.

I have been asked to review and comment upon the 57-page, undated Affidavit of Dr. John W. Martyny. I have also reviewed two binders of documents, one containing communications and warnings provided by BW to Raytheon and the other containing Raytheon policies, procedures and other documents. My compensation will be at the rates of $400 per hour for consultation and $475 per hour for testimony. A list of my testimony during the past four years is attached.

1. Background

It is my understanding that Ms. Suzanne Genereux worked at the Raytheon facility in Waltham, Massachusetts from May, 1982 until November, 1990. She now claims that she developed chronic beryllium disease (CBD) as a consequence of exposures that occurred while she worked at Raytheon.

In his Affidavit, Dr. Martyny argues that:

a) Brush Wellman (BW) "knew or should have known" that Ms. Genereux was being subjected to "overexposure" to beryllium;

b) BW repeatedly "downplayed" the hazards associated with her beryllium exposures.

c) BW "allowed" her to be exposed at "levels that exceeded levels known to cause CBD";

As discussed below, however, the opinions presented by Dr. Martyny are based mainly on data published after Ms. Genereux no longer worked at Raytheon. Such data provide no basis for concluding what was known at the time that Ms. Genereux worked; they inform us only about what was known after she stopped working. Accordingly, I find his argument to be illogical. Whether she was "allowed" to be exposed at "levels that exceeded levels known to cause CBD" can only be meaningfully judged in light of that which was "known" at the time she worked, not in light of that which would become known at some future time.

Also, as discussed below, it is not evident that BW had the operational capacity to "allow" or "disallow" specific work practices at the Raytheon facility and Dr. Martyny provides no support for that opinion.

Furthermore, as discussed below, I find no basis to assert that BW "downplayed" the hazards that might have been associated with the processes or employment at the Raytheon facility. To the contrary, it is my opinion that the BW communications accurately reflected the then-current state of scientific knowledge.

2. Historical Perspectives

Throughout the time that Ms. Genereux worked at Raytheon, there was a consensus occupational exposure limit (OEL) of 2 $\mu g/m^3$ for beryllium. The history of the development of that standard and its acceptance by AEC, ACGIH, ANSI, OSHA, NIOSH, and others have recently been reviewed (1). It is notable that as of today, in 2006, that OEL remains the standard for both OSHA and ACGIH; no alternative OEL has been adopted by either organization.

In his Affidavit, Dr. Martyny asserts that the 2 $\mu g/m^3$ OEL standard "has been questioned since the mid-1980's". His statement is based on the fact that "in the early 1980's ... CBD returned to the scene":

> "Immediately after the setting of the AEC beryllium exposure standard, it seemed that the lowered exposure levels were controlling CBD. In the early 1980's, however, CBD returned to the scene." (Affidavit, p. 24)

In support of that assertion, he offers four studies published prior to 1990 and a greater number of studies and other documents published after 1990. I comment on the first four below; I will not comment specifically on the cited studies published after 1990 because they could not have informed thinking about beryllium during the time that Ms. Genereux was employed at Raytheon.

2a) The first study cited by Dr. Martyny was a 1983 report of three workers employed at a spacecraft manufacturing plant who developed CBD (3). However, the report indicates that all three "worked with beryllium metal from the late 1950s to the mid-1970s" and furthermore that from 1963 to 1973, "14 to 44% of samples taken at the machine shop exceeded" the OEL. Nothing in this report suggests or asserts that that these workers were not regularly exposed to levels exceeding the OEL. To the contrary, on the basis of the limited data in this report, it is probable that they were overexposed at least 14 to 44% of the time.

Thus, this report provides no evidence that the OEL was not adequate to prevent CBD and it fails to support the opinions of Dr. Martyny.

2b) The second study cited by Dr. Martyny was a 1983 study of beryllium miners (4). The authors' stated objective was to study beryllium lymphocyte transformation, not CBD, and none of the workers had CBD: "No cases of CBD or pneumoconiosis were found." Also, exposure data were very limited. The miners, evaluated in 1979 and 1982, had worked at the mine for up to 14 years, but no exposure data were reported prior to 1979. Moreover, for the entire year of 1979, there were only 27 exposure samples, of which 33% exceeded the OEL; the average exposure level that year, when all study subjects were working, was 7.19 ug/m^3, nearly four times the OEL.

Thus, this study documented no cases of CBD despite exposures significantly greater than the OEL. It provides no evidence that the OEL was not adequate to prevent CBD and it fails to support the opinions of Dr. Martyny.

2c) Dr. Martyny also cited a 1987 study by Cullen et al. that reported CBD in five workers at a precious metal refinery (5), where (according to Dr. Martyny) "air concentrations of beryllium were felt to be below the current 2 ug/m^3 standard." Four of the five worked in the furnace area between 1964 and 1977; the fifth worked in other refinery areas from 1969 to 1983. Exposure data were limited to two one-week surveys performed in 1983. Levels in the furnace area averaged <2 µg/m^3, but time-weighted-average personal samples throughout the plant ranged up to 42.3 µg/m^3. Overall, 10% of samples were >2 µg/m^3 and levels outside the furnace area, where the affected workers were sometimes exposed, were "often much higher than the standard" (5).

Cullen et al. described at least four considerations that raise doubts that workers were only exposed to levels <2 µg/m^3: There were only a limited number of samples; sampling was performed years after the workers had left the refinery; high levels were seen in areas where the affected workers would have been exposed; and, the sampling method may have underestimated exposure levels near the furnaces "where beryllium is likely to be in the form of a fine fume, unlike the dust exposures elsewhere" in the refinery (5).

These concerns were also voiced in the 1993 ATSDR *Toxicology Profile for Beryllium*, which questioned the study findings because of: "underestimation of exposure levels … measurement of levels only in 1983, although exposure occurred between 1964 and 1977; limited sampling, which … may have missed high concentrations; the possibility that the workers in question were also exposed to high levels … outside the furnace area…" (6).

A similar concern about this study was raised by Dr. Martyny's National Jewish Medical Center colleagues in a recent edition of *Patty's Toxicology*:

> "the beryllium air concentrations measured retrospectively over a 2-week period in this study may not be representative of exposures over the previous 20 years" (7), p.203.

Thus, it is not surprising that the Cullen study was viewed with skepticism and that its findings were not generally accepted as showing that the 2 µg/m^3 standard was not adequately protective. For those reasons, the study fails to support the opinions of Dr. Martyny.

2d) The fourth pre-1990 study cited by Dr. Martyny was a 1989 study of 51 workers: 24 research and development (R&D) workers and 27 production workers (8). The authors' stated objective was to evaluate a screening blood test; the study detected four cases of sub-clinical beryllium disease. However,

no exposure data were reported. However, the authors state that mandatory use of respirators had been implemented five years earlier because a case of CBD was diagnosed in a worker and, presumably, because exposure levels exceeded the OEL.

The R&D workers averaged >21 years since first beryllium exposure, while the production workers averaged more than five years; some production workers were hired at the time that the respirator program was implemented, but some had worked for more than 10 years. From this, I conclude that the majority of these workers had been exposed to beryllium at the facility for years prior to the mandatory respirator program, when exposure levels exceeded the OEL [1].

All but one of the workers with positive blood tests were R&D workers, the group with the longest duration and highest levels of beryllium exposure. However, the authors were unable to correlate exposure levels to CBD. Thus, this report provides no evidence that the OSHA beryllium standard was not adequate to prevent CBD and it fails to support the opinions of Dr. Martyny.

2e) Dr. Martyny also indirectly references the work of Shima, which he describes on page 25 as follows:

> "A study by Yoshida and Shima, et al (the latter producing similar work implicating health risks below 2 ug/m^3 dating back to the 1970's), indicated beryllium sensitized workers in a beryllium copper plant even though exposures were measured to be below the current standard."

It is notable that the cited study by Yoshida et al. (9) neither describes nor cites Shima's "similar work dating back to the 1970's". However, I assume that Dr. Martyny is referring to a series of reports beginning in 1974 describing 15 cases of CBD in Japanese beryllium workers at facilities where exposures were reported to be "much lower than 2 µg/m^3" (10,11). However, as described below, there are reasons to believe that the Shima reports significantly underestimated worker exposures.

First, the exposure data in the Shima reports were obtained following then standard Japanese industrial hygiene protocols that relied on area samplers

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[1] Dr. Martyny also cited a 1993 report for the same facility (23), of which he was an author, that provided more information about exposures. The authors stated that historical data available since 1959 were of only "limited" usefulness for characterizing exposure trends. They also noted that in 1984, after the first diagnosed case of CBD, the plant installed ventilation equipment that "substantially lowered beryllium exposures for machining operations". Finally, they concluded that "we could not reconstruct quantitative historical job-specific exposure estimates."

Thus, it is apparent that like the 1989 report (8), this 1993 report (23) is not relevant to Dr. Martyny's opinion that the OEL was not adequately protective. However, it confirms that exposures were "substantially" higher prior to 1984.

placed geometrically throughout the work area, rather than in workers' breathing zones or specifically near high-exposure tasks (12,13). (Yoshida et al. also used the "area sampling method" (9)).

But elsewhere in the Affidavit, Martyny emphasizes that area samplers generally understate worker exposure and he cites findings that results of area sampling are often not comparable to personal respirable sampling results. Given that the Japanese method utilized area samplers that were distributed geometrically, rather than near specific work areas or workers' breathing zones, and in consideration of the arguments and data presented in the Martyny Affidavit about the limitations of area samples, one must conclude that the workers were exposed to higher levels than those reported by Shima.

Second, it is noteworthy that Shima also described 27 cases of acute beryllium pneumonitis among facility workers (10,11). Because acute beryllium pneumonitis had been associated with only very high exposure levels (e.g., >100 $\mu g/m^3$) (7,14), those cases indicate that facility exposures must have been substantially greater than 2 $\mu g/m^3$.

Thus, the Shima reports provide no evidence that the OEL was not adequate to prevent CBD, and they fail to support the opinions of Dr. Martyny.

3. Further Historical Perspectives

As just described, the studies cited by Dr. Martyny do not support his opinion that from 5/82 until 11/90, when Ms. Genereux worked at Raytheon, there were substantial questions whether the beryllium OEL was adequately protective against CBD. To the contrary, as reviewed below, the literature indicates that there was a substantial basis for believing that it was protective.

Implementation of the 2 $\mu g/m^3$ OEL did not occur 'overnight'. The year 1960 represents the approximate date when most facilities were able to achieve the standard, although there is evidence that the OEL was still often exceeded (15). Nevertheless, there was a widely shared sense that the new standard was effective, perhaps even overly protective (16,17). In 1972, for example, the NIOSH *Criteria Document for a Recommended Standard: Occupational Exposure to Beryllium* endorsed the 2 $\mu g/m^3$ standard:

> "The standard recommended in this document is similar to that adopted by the AEC in 1949 and the present OSHA environmental standard. It is felt to be feasible technologically for the control of worker exposure to beryllium and effective biologically for protection of the worker from acute and chronic beryllium disease." (18) p.VI-5, (emphasis added)

The view that the 2 μg/m^3 OEL was adequately protective was also supported by apparently compelling evidence provided by the experience of the Department of Energy at its Rocky Flats and Oak Ridge Y-12 plants. The following narrative is from a recent GAO report:

> "from the 1970s through 1984, the incidence of CBD appeared to significantly decline at Energy facilities. This apparent reduction, along with the long latency period for the disease, led Energy to assume that CBD was occurring only among workers who had been exposed to high levels of beryllium decades earlier, such as in the 1940s. However, a new case of CBD was diagnosed in a worker employed in 1970 at Energy's Rocky Flats facility ... Energy's Albuquerque Operations Office, which oversaw Rocky Flats, conducted an investigation of working conditions at the plant's beryllium machine shop to identify factors contributing to the disease case. The investigation, reported in October 1984 ... found that the affected worker had repeatedly been exposed to beryllium at levels greater than the PEL of 2 μg/m^3 of air (averaged over an 8-hour period)." (19), p. 9.

Thus the experience of the Department of Energy through the 1980s also supported the view that the OEL was protective.

Additional support was also provided by an absence of CBD cases at the Cardiff beryllium facility in the UK. The Cardiff facility was recognized for its "stringent exposure controls" designed to maintain airborne levels <2 μg/m^3 and also for its lack of CBD cases in its workforce. Historical Cardiff exposure data have recently been reviewed (20). During its operations from 1961-97, there were 367,757 area samples obtained throughout the facility (16,000-25,000 per year), of which less than 0.1% exceeded 2 μg/m^3. There were also 217,681 personal samples obtained. Over all the years of operation, 99.5% of the personal samples were <2 μg/m^3. Highest exposures occurred in the foundry area, where the median level was 0.22 μg/m^3 and the 95% percentile of all samples was 2.92 μg/m^3. Because respiratory protection was worn for high-risk foundry work, exposures were almost certainly less than suggested by the sampling data.

During its 38 years of operations, more than 400 workers were employed at Cardiff, but only one clinical case of CBD was diagnosed. That case, diagnosed in 1963, involved a worker with a beryllium-contaminated finger laceration that progressed to systemic beryllium disease. Cardiff did not have a single case of CBD due to inhalation exposure.

The experience at BW was similar. Among nearly 3000 employees hired by BW between 1960 and 1981, only two cases of CBD were diagnosed and both had evidence of exposure substantially greater than the 2 μg/m^3 OEL (21). The significance of having encountered only two cases during that 21-year time span is underscored by consideration of the size, scope and complexity of BW

operations. For example, Cardiff scientists juxtaposed their relatively small facility to the much larger, complex operations at BW:

> "It is noteworthy that the Cardiff facility was unlike the large mining, processing, or manufacturing facilities at BW where thousands of tons of various kinds of beryllium were handled annually... The differences in the quantity and form of beryllium materials handled should be considered when comparing exposure and epidemiology studies of other facilities including the BW sites in Elmore (Ohio), Delta (Utah), Tucson (Arizona), Reading (Pennsylvania), and Lorain (Ohio)..." (20), p.620.

In other words, the scope, size and complexity of beryllium operations at BW were substantial. Even if it had not been possible to attribute those two cases to specific exposures exceeding 2 $\mu g/m^3$, such a low incidence rate would have been remarkable and praiseworthy. It is difficult to believe that under any circumstances, those cases could have raised substantial doubts about the 2 $\mu g/m^3$ standard.

Thus, during these years, there was substantial basis to believe that the 2 ug/m^3 occupational exposure standard was adequate to protect against development of CBD. There was not sufficient evidence to suggest that it was inadequately protective.

4. Importance of the Historical Context

In his Affidavit, Dr. Martyny argued that in light of information published after 1990, it should have been known before 1990 that the beryllium OEL was not adequately protective. Such an approach is inherently illogical. More generally, the Martyny Affidavit fails to provide scientific support for his view that the beryllium OEL was known or should have been known to be insufficiently protective during the period when Ms. Genereux worked at Raytheon.

There is particular importance to the historical perspective in this matter (i.e., *what was known and when was it known*) because Dr. Martyny repeatedly criticizes BW for failing to meet certain 'standards', but those 'standards' are not objectively defined in his Affidavit and could only be meaningfully defined in their historical context.

For example, on pages 47-48, he discusses a BW MSDS from the "early 1980s", which states that exposure to "excessive amounts of respirable beryllium" may cause serious health effects. It is my understanding that the term "excessive amounts of respirable beryllium" specifically referred to levels greater than the 2 ug/m^3 beryllium OEL.

Dr. Martyny characterizes that MSDS as "extremely poor hazard information", but his characterization criteria are unclear. I think that he disagrees with the term

"excessive amounts of respirable beryllium", because his Affidavit goes on to say:

> "Two ug/m^3 of dust is invisible and certainly would not be considered to be an 'excessive amount' of dust."

There are two possible meanings to that sentence. One is that Dr. Martyny believes that in the "early 1980s", it was known that the 2 ug/m^3 OEL did not meaningfully distinguish "excessive" exposures and was not adequately protective. As I have discussed above, however, the Martyny Affidavit provides no scientific evidence to support that view.

The second possibility is that Dr. Martyny believes that a worker might think that if the level of beryllium particulate in air were invisible ("can't even be perceived by the human eye"), then that level would not be "excessive". In other words, he proposes that Raytheon workers might have assumed that beryllium exposure levels were not excessive if the beryllium was not visible.

However, I know of no support for that proposal. To the contrary, I am not aware that 'visibility' is used as the basis for determining occupational exposure limits for any workplace chemicals. Likewise, I am not aware of any approved training systems that teach workers to judge the safety of their workplace on the basis of whether they can see chemicals in the air. In addition, there are numerous examples of chemicals (including dusts and fumes) with consensus exposure limits at levels that cannot be detected visually.

Similar objections are raised on pages 45-46 of the Affidavit regarding use of the terms "significant amounts" and "high concentrations" in a 1989 letter from BW to Raytheon that warned about the hazards of exposure to "significant amounts of respirable beryllium" and "high concentrations of particulate". It is my understanding that the terms "significant amounts of respirable beryllium" and "high concentrations of particulate" referred specifically to levels greater than the 2 ug/m^3 OEL.

Dr. Martyny disagrees with that letter, but the basis of his disagreement is not clear. As in the prior example, there are seemingly two explanations. One is that he believes that it was then known that the 2 ug/m^3 OEL did not adequately distinguish "excessive" exposures and was not adequately protective. The other is that Dr. Martyny believes that "significant amounts" and "high concentrations" are incorrect terms because at 2 ug/m^3, beryllium "can't even be perceived by the human eye". But, as I discussed previously, there are no scientific data to support either of those possibilities and Dr. Martyny provides no scientific support for his opinions.

In any event, it should be clear that appropriate criteria for defining the concepts of "significant", "excessive" and "high" beryllium exposure during 1982-1990 should have been objective and based upon then-existing scientific data. In light

of the published scientific literature and the actual experience of DOE, BW, Cardiff and others, it is obvious that during that period only workplace exposure levels exceeding the 2 ug/m^3 OEL could have been reasonably regarded as "significant", "excessive" or "high".

Subsequent to 1990, as detailed in my 2006 review of the beryllium OEL (1), there were significant advances in knowledge about beryllium and CBD. Those advances were largely a result of evolving medical technology that allowed researchers to more readily detect beryllium sensitization and diagnose subclinical CBD. Many of the studies that advanced this knowledge were funded by BW and performed on BW workers. As the knowledge evolved, BW modified the information that it communicated to its workers and customers.

5. Did BW "Downplay" the Hazards?

In his Affidavit, Dr. Martyny repeatedly argues that BW understated the risks and hazards associated with beryllium exposures at the Raytheon facility. For example, on pages 44-45 he discusses "several letters from BW to Raytheon indicating that sandblasting would be a problem". He also acknowledges that in 1984 Marc Kolanz:

> "warned Mr. John Skowron of Raytheon about sandblasting beryllia and in August 1986 he warns Mr. Peter Salvatore of Raytheon of the same concern."

Somehow, these repeated warnings have been interpreted by Dr. Martyny as examples of how Kolanz "downplays the level of concern" by indicating that sandblasting "can generate airborne beryllium levels above the occupational exposure limit". I find his criticism to be without merit. Moreover, he has essentially quoted out of context, in a manner that misrepresents the Kolanz letter to Mr. Skowron, which I quote below:

> "The sandblasting of beryllia … can generate airborne beryllium levels above the occupational standard and is not recommended. High air levels may occur from sandblasting due to inadequate air flow, hood leakage, beryllium contamination of the blasting medium, or material handling… Inhalation of concentrations of beryllium in excess of the Occupational Standard described below can cause serious lung disorders."

That statement, written in 1984, seems correct, appropriately reflecting the then-current state of scientific knowledge.

Moreover, the Kolanz statement seems consistent with a statement made by Dr. Martyny on page 45:

> "sandblasting or gritblasting of beryllia in an uncontrolled fashion will result in an over exposure to employees."

If there is a difference between the Kolanz and Martyny statements, it reflects merely that Kolanz said that sandblasting "can" generate excessive levels, while Dr. Martyny says that it "will" generate such levels. But Dr. Martyny offers no evidence that such an outcome would necessarily be inevitable, therefore it is my opinion that the difference between their two statements is trivial and without operational significance.

I have similar concerns about other statements in the Martyny Affidavit. For example, on page 43 it states that "BW [and others] knew or should have known of the high potential for overexposure to beryllium" and then, on page 44, it complains that a letter from BW to Raytheon:

> "downplays the hazards of beryllium handling. The letter cites 'a potential health risk' if beryllium is abraded to form a finely divided airborne particulate."

The complete statement from the letter of 8/29/93 from Kolanz to Demeo actually says:

> "A potential health risk can occur when grinding, machining, sanding, drilling, brazing, welding, or otherwise abrading or treating the surface in such a manner so as to generate finely divided airborne particulate. ... If you intend to do any of these functions, please contact me for further information."

I cannot understand the basis for Dr. Martyny's opinion that this reflects an effort to "downplay" the hazards. If there is a difference here between Kolanz and Martyny, it reflects merely that Kolanz said there was a "potential health risk" while Martyny said there was a "high potential for overexposure". If one believes that "high potential overexposure" is associated with "a potential health risk", then these two statements are entirely compatible, differing only in whether the focus is the exposure (as discussed by Martyny) or the health effect (as discussed by Kolanz). Thus it is my opinion that the objections raised by Dr. Martyny are trivial and without operational significance.

Moreover, I have seen numerous letters from BW to Raytheon in which the potential hazards of beryllia and beryllium particulate are repeatedly discussed. Note for example the following letters which represent an incomplete list:

6/7/84: Kolanz to Mort Sullivan
8/8/86: Kolanz to Peter Salvatore
12/9/86: Powers to Von Going
3/24/87: Powers to Shirley Gates
10/6/87: Kolanz to Roger Harsh
3/3/89: Kolanz to Walter Hartford

In summary, I have seen no evidence that BW "downplayed" the hazards of handling beryllium. To the contrary, they made repeated efforts to inform and warn Raytheon of the potential hazards. With respect to this part of the Martyny Affidavit, it is my opinion that his objections are trivial and without operational significance. Moreover, I find that Dr. Martyny failed to provide evidence or scientific support for his opinion.

6. Did BW "Allow" Operations at the Raytheon Plant?

In his Affidavit, Dr. Martyny asserts that BW "allowed workers at the Raytheon plant" to be overexposed to beryllium and "made no attempt to employ available technology at the facility…". I find these assertions puzzling in light of my understanding of the terms used in the Affidavit.

Dictionary definitions of the verb "allow" include "to give permission" and "to permit by neglect". I find neither of these (or the other dictionary definitions) to apply in this setting. To the contrary, as discussed above, I have seen numerous letters and communications between BW and Raytheon in which the potential hazards of beryllia and beryllium particulate are repeatedly discussed. That record of communications seemingly refutes concerns about 'neglect'. On the other hand, I am aware of no standards in the 1980s that required a supplier to review and permit the use of its products as intermediates by other, sophisticated manufacturing companies. Accordingly, I find that use of the term "allow" is not appropriate in this context.

Likewise, it is not apparent to me that BW was in a position legally or otherwise to "employ … technology" at the facilities of other manufacturing companies. I am also unaware of any standards in the 1980s that required a supplier to "employ … technology" at the facilities of other, sophisticated manufacturing companies that used its products as intermediates in their own activities. Accordingly, I find that use of the term "made no attempt to employ" is not appropriate in this context.

7. BW and the Forefront of Beryllium Research

In his affidavit, Dr. Martyny states that BW was not at the forefront of concern about the adequacy of the OEL. On page 29 he accuses BW of being at the "end of the movement":

> "In my opinion, BW should have been in the forefront of that movement not at the end of the movement."

This statement is incorrect. To the contrary, BW has long been a major sponsor of research on the health effects of occupational beryllium exposure and their

relation to the OEL and has served as a leader in promoting a scientific understanding of these issues.

BW supported numerous research studies and reports by Dr. Martyny and his colleagues at National Jewish (NJMC) by providing the necessary funding and by allowing access to its workers at two facilities. The agreements between BW and NJMC [2], signed in 1992 and 1993, funded NJMC to develop and administer worker questionnaires, to review all personnel rosters, all medical surveillance data, and all industrial hygiene data, to estimate historical exposures, and to integrate that information with individual work and job histories. In addition, BW paid for testing and clinical evaluations on a fee-for-service basis. BW also gave NJMC unrestricted use of the research findings:

> "National Jewish may . . . use Brush Wellman data in statistical compilations and researchers shall likewise be able to use the data and the statistical correlations. . . . Brush Wellman does not reserve in any way the right to control, direct or censor conclusions or report dissemination."

Several years later, BW entered into an agreement with researchers at NIOSH that provided funding and access to its workers for research performed by NIOSH scientists. As in the earlier NJMC agreements, BW specifically gave the NIOSH researchers complete control over the data:

> "In the event of disagreement regarding interpretation or analyses, each party retains the right to disseminate their work."

The agreement between BW and NIOSH was so open and fair that the NIOSH Board of Scientific Counselors judged it to be "a model for similar work with industry groups" (22).

It is my understanding that BW gave free access to its workers and financial support to the NJMC and NIOSH researchers because it was committed to better understanding the relationship between beryllium exposure and disease. It is inconceivable to me that BW would have provided such funding and access to its workers if it had not sincerely wanted to ensure a better understanding of the hazards of beryllium exposure [3].

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[2] These agreement were entered into evidence in Ballinger v. BW as Defense Exhibits 1835 and 1836.

[3] I note that three of the studies cited by Dr. Martyny as evidence against BW (Rom et al. 1983; Kreiss et al. 1996; Kreiss et al. 1997) were actually funded by BW and performed on BW workers. Two of those studies (24,25), performed under the service agreements described above in footnote [2], contain the following acknowledgement:

> "We thank the company management and medical department staff for their vision in allowing this study..."

Contrary to the accusations in the Martyny Affidavit, these actions demonstrate that BW assumed a leadership role in advancing scientific understanding about beryllium and CBD.

Accordingly, contrary to assertions made by Dr. Martyny, it is my opinion that BW played a leadership role in evaluating the adequacy of the OEL by among other things funding and supporting research by NJMC, NIOSH and others on the relationship between occupational exposures to beryllium and CBD.

8. Summary

In summary, it is my medical and scientific opinion that prior to 1990, during the time that Ms. Genereux was employed at Raytheon, there was insufficient scientific data to support the view that the 2 ug/m^3 OEL was not adequately protective. To the contrary, it is my opinion that the weight of evidence supported the view that the OEL was adequately protective.

It is also my opinion that the communications and warnings provided by BW to Raytheon during the time that Ms. Genereux was employed were consistent with the scientific information that was then available.

Jonathan Borak, MD, DABT

It is striking that Dr. Martyny was an author of one of those reports (24). It seems at least inconsistent, and perhaps disingenuous that on the one hand Dr. Martyny lavished praise on BW for its "vision" (which I interpret as reflecting its foresight and leadership), while on the other hand he criticizes BW for not being at the forefront.

8. References

1. Borak J: The beryllium occupational exposure limit: historical origin and current inadequacy. J Occup Environ Med 48:109-116, 2006.

2. Borak J, Woolf SH, Fields CA: Use of beryllium lymphocyte proliferation testing for screening of asymptomatic individuals: An evidence-based assessment. J Occup Environ Med 48:937-947, 2006.

3. Beryllium disease among workers in a spacecraft-manufacturing plant - California. MMWR 32:419-425, 1983.

4. Rom WN, Bang KM, Dewitt C, et al.: Reversible beryllium sensitization in a prospective study of beryllium workers. Arch Environ Health 38:302-307, 1983.

5. Cullen MR, Kominsky JR, Rossman MD, et al.: Chronic beryllium disease in a precious metal refinery. Am Rev Respir Dis 135:201-208, 1987.

6. Agency for Toxic Substances and Disease Registry: Toxicological Profile for Beryllium (TP-92/04). Washington, DC: US Department of Health and Human Services, 1993.

7. Mroz MM, Balkissoon R, Newman LS: Beryllium. In: Bingham E, Cohrssen B, Powell CH (eds): Patty's Toxicology, Volume 2, Toxicological Issues Related to Metals/Neurotoxicology and Radiation/Metals and Metal Compounds, New York: John Wiley & Sons, pp. 177-219, 2000.

8. Kreiss K, Newman LS, Mroz MM, et al.: Screening blood test identifies subclinical beryllium disease. J Occup Med 31:603-608, 1989.

9. Yoshida T, Shima S, Nagaoka K, et al.: A study on the beryllium lymphocyte transformation test and the beryllium levels in working environment. Ind Health 35:374-379, 1997.

10. Shima S: Beryllium poisoning and health care. Sangyo Igaku 3:14-22, 1980.

11. Shima S: A suggestion concerning medical prevention and control of chronic pulmonary berylliosis. Rodo Eisei 8:18-24, 1974.

12. Koshi S: A basic framework of working environment control for occupational health in Japan. Ind Health 34:149-166, 1996.

13. Ministry of Labour: Working Environment Measurement System in Japan. Tokyo: Japan Association for Working Environment Measurement, 1991.

14. Eisenbud M: Origins of the standards for control of beryllium disease (1947-1949). Environ Res 27:79-88, 1982.

15. Eisenbud M: The standard for control of chronic beryllium disease. Appl Occup Environ Hyg 13:25-31, 1998.

16. Tepper LB, Hardy HL, Chamberlin RI: Toxicity of Beryllium Compounds. Amsterdam: Elsevier, 1961.

17. Cholak J, Kehoe RA, Miller LH, et al.: Toxicity of Beryllium: Final Technical Engineering Report (ASD-TR-62-7-665). Cincinnati: University of Cincinnati, 1962.

18. National Institute for Occupational Safety and Health: Criteria for a Recommended Standard ... Occupational Exposure to Beryllium. Washington, DC: U.S. Department of Health, Education and Welfare, 1972.

19. US General Accounting Office: Government Responses to Beryllium Uses and Risks (GAO/NSIAD/RCED/HEHS-00-92). Washington, DC: US Government Printing Office, 2000.

20. Johnson JS, Foote K, McClean M, et al.: Beryllium exposure control program at the Cardiff Atomic Weapons Establishment in the United Kingdom. Appl Occup Environ Hyg 16:619-630, 2001.

21. Preuss OP: A contribution to the epidemiology of beryllium disease. In: Gee JBL, Morgan WKC, Brooks SM (eds): Occupational Lung Disease, New York: Raven, pp. 223-224, 1984.

22. NIOSH Board of Scientific Counselors: Report from the Subcommittee on Beryllium Research. Atlanta: Centers for Disease Control and Prevention, 2002.

23. Kreiss K, Mroz MM, Zhen B, et al.: Epidemiology of beryllium sensitization and disease in nuclear workers. Am Rev Respir Dis 148:985-991, 1993.

24. Kreiss K, Mroz MM, Newman LS, et al.: Machining risk of beryllium disease and sensitization with median exposures below 2 $\mu g/m^3$. Am J Ind Med 30:16-25, 1996.

25. Kreiss K, Mroz MM, Zhen B, et al.: Risks of beryllium disease related to work processes at a metal, alloy and oxide production plant. Occup Environ Med 54:605-612, 1997.